IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civ. Action No. 05-356-SLR (consolidated)

DEFENDANTS BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S REDACTED ANSWERING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

It is black letter law that patent claim terms are to be given their plain and ordinary meaning. While Plaintiffs readily acknowledge this well-known standard in their brief, their proposed claim constructions radically depart from it. In short, Plaintiffs want this Court to adopt constructions of the asserted claim terms that are unfaithful to, and in some cases contradict, the claim language and intrinsic evidence. Plaintiffs' motivations for doing so are clear: Plaintiffs want to avoid a wealth of invalidating prior art and a finding that the asserted claims are not enabled.

Unlike Plaintiffs' constructions, Barr's constructions are supported by the claim language and intrinsic evidence and are faithful to the plain and ordinary meaning of the claim terms. The terms "patient," "related dementias," "treating," and "therapeutically effective" are frequently used terms in the medicinal art. Nothing in the claim language or intrinsic evidence suggests that they should be interpreted to have a meaning other than their plain and ordinary meaning.[1] For at least these reasons, Barr's proposed constructions should be adopted and Plaintiffs' constructions rejected.

II. CLAIM CONSTRUCTION OF DISPUTED TERMS

A. "Alzheimer's disease and related dementias"

The parties agree the term "Alzheimer's disease" has been defined with specificity in the patent specification to mean "presenile dementia." (Plaintiffs' Br. at 9). The parties *disagree* on the meaning of the term "and related dementias." Plaintiffs, without so much as a cite to either the claim language or patent specification, maintain that the phrase "related dementias" means

[1] This Court, therefore, should disregard Plaintiffs' recitation of the law as it pertains to the appropriateness of construing claim terms to preserve their validity. (Plaintiffs' Br. at 5-6). It is not the function of the Court to rewrite claims to preserve their validity. *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002). This is particularly true where a claim is "susceptible of only one reasonable construction." *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1309 (Fed. Cir. 2000).

only senile dementia of the Alzheimer's type. Barr, on the other hand, contends that the phrase is not so limited. Rather, the term means what it says: dementias related to Alzheimer's disease. Plaintiffs' construction should be rejected for at least the following reasons.

First and foremost, Plaintiffs' proposed construction contradicts the plain language of the claim. The claim language is clear: "related dementias." (U.S. Patent No. 4,663,318, claim 1 (emphasis added)).[2] It is not "related dementia" or "senile dementia of the Alzheimer's type," which is the constructions that Plaintiffs would have this Court adopt. If Plaintiffs' construction were adopted, the Court would have to ignore the exact language of the claim and rewrite the word *dementias* in the singular. Such a construction is legally incorrect. After all, claim interpretation begins with the actual words of the claims. *Bell Communications Research v. Vitalink Communications Corp.*, 55 F.3d 615, 619-20 (Fed. Cir. 1995). A court cannot "rewrite claims and must construe the language of the claim at issue based on the words used." *SRAM Corp. v. AD-II Engineering, Inc.*, 465 F.3d 1351, 1359 (Fed. Cir. 2006). Furthermore, words not present in the claims cannot suddenly become claim limitations. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1325 (Fed. Cir. 2003) (noting that it is improper to import a limitation into a claim where the purported limitation "is based upon a term not appearing in the claim.").

Plaintiffs offer no explanation for why the phrase "related dementias" (plural) should, in fact, be read to encompass only senile dementia of the Alzheimer's type (singular).[3] Plaintiffs do not (and cannot) dispute that the claim language is written in the plural with respect to "dementias," the phrase also appears in the patent specification and prosecution history in the

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[2] All references to "Exhibit _" or "Ex. _" refer to the exhibits attached to the Declaration of Brian E. Farnan filed contemporaneously herewith. A copy of the '318 Patent is attached to the Farnan Declaration as Exhibit 1.

[3] As noted above, the Parties are in apparent agreement that "Alzheimer's disease," as used in claim 1, refers only to "presenile dementia."

plural, not singular, form, and nowhere in the prosecution history does the inventor use the terminology senile dementia of the Alzheimer's type.

Moreover, Plaintiffs cannot dispute that the term "related dementias" was a term that was used by persons of ordinary skill in the art and had a defined meaning that included dementias beyond senile dementia of the Alzheimer's type.

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Second and tellingly, the primary evidence that Plaintiffs have advanced in support of their proposed construction of "related dementias" is extrinsic evidence. In this case, resort to extrinsic evidence at all, including expert testimony and opinion, is unnecessary because the meaning of the terms can be derived from the intrinsic evidence, namely, the claim language itself. *See, e.g., Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581 (Fed. Cir. 1996). It is a "rare circumstance" where the court is unable to determine the meaning of a disputed claim term after assessing the intrinsic evidence alone. *Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268-69 (Fed. Cir. 2001).

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Plaintiffs so-called intrinsic evidence (the Hershenson and Moos article) also does not support Plaintiffs' construction. ("Drug Development for Senile Cognitive Decline" by Fred M. Hershenson and Walter H. Moos, attached to the Farnan Declaration as Exhibit 4). At the outset, it is debatable whether the article should be viewed as intrinsic evidence at all given that the reference was not published until after the date the '318 patent application was filed and therefore, is not prior art.

Moreover, regardless of whether the article is considered to be intrinsic evidence, the article simply does not support Plaintiffs' argument that the term "related dementias" must mean *only* senile dementia of the Alzheimer's type. The article does not use the term "related dementias" at all, much less define it to mean *only* senile dementia of the Alzheimer's type. Interestingly, when discussing senile dementia of the Alzheimer's type, the article refers to the condition as primary degenerative dementia (PDD), and the authors make a point of stating that the condition also is referred to as "senile dementia, senile dementia of the Alzheimer's type, Alzheimer's disease, [and] organic brain syndrome." (Ex. 4 at JAN RAZ-0000043). They do not state the condition is referred to as "related dementias." Thus, if Dr. Davis intended to limit her invention to senile dementia of the Alzheimer's type as Plaintiffs now claim, she could have done so by using the term PDD or any of the other terms used by Hershenson and Moos to describe PDD. She did not. Rather, Dr. Davis chose to use the broad term "related dementias," which by its very definition necessarily encompasses more than senile dementia of the Alzheimer's type. **REDACTED**

In sum, the Court should reject Plaintiffs' invitation to rewrite claim 1 to read "senile dementia of the Alzheimer's type." Because the term "related dementias" is clear and

unambiguous on its face and Dr. Davis did not define the term to mean *only* "senile dementia of the Alzheimer's type," the Court should adopt Barr's construction.

B. "Patient"

The dispute between the parties over the meaning of "patient" turns on whether the term means "mammals, including humans", as Barr contends, or *only* humans, as Plaintiffs contend. Barr's construction is supported by the intrinsic evidence. Plaintiffs' construction is not.

First, when describing her invention, the inventor stated in no uncertain terms that the target or recipients of her so-called invention were "mammals, including humans." The written description states "a method of treating Alzheimer's disease and related dementias which comprises administering galanthamine to mammals, including humans." (Ex. 1 at 1:45-50). Thus, when read in context, as Plaintiffs urge the Court to do, the intrinsic evidence supports Barr's reading of "patient" as meaning "mammals, including humans."

Recognizing that they do not have any sound evidence to refute Barr's construction, Plaintiffs resort to arguing that the Court does not need to construe the term "patient" because Barr either has not put the term at issue through its expert reports, or alternatively, Barr has not identified any mammals, other than humans, that suffer from Alzheimer's disease. Plaintiffs' criticisms are without merit.

First, Plaintiffs have waived their right to assert a construction of "patient" because they did not comply with the Court's Revised Scheduling Order. Specifically, on November 10, 2006, the parties were to exchange a list of claim terms for the Court to construe. Plaintiffs did not list "patient" among their terms. On November 27, 2006, as required by the Scheduling Order, the parties held a meet and confer to discuss their respective claim constructions. Barr specifically asked Plaintiffs if they disagreed with Barr's construction of "patient." Plaintiffs

claimed that they were still looking at the issue. The first time that Barr received Plaintiffs' proposed construction of "patient" was on November 30, 2006, when the parties filed their respective claim construction briefs. Because Plaintiffs' proposed construction was untimely, Plaintiffs have waived their right to assert the term now.

Even if the Court were to consider Plaintiffs' proposed construction, it should be rejected on the merits. Plaintiffs have not cited a single case that puts the burden on Barr to identify what mammals, other than humans, suffer from Alzheimer's disease and related dementias so as to put the term "at issue" for claim construction. Even if Barr has such a burden, which it does not, Barr has met it. Whether the term "patient" is construed alone or as part of the phrase "patient suffering from such a disease," as Plaintiffs contend it must be, the result is the same. The specification states on its face that the invention applies to "a method of treating Alzheimer's disease and related dementias . . . in mammals, including humans . . ." (Ex. 1 at 1:45-50). Thus, the patent inventor described her invention as covering mammals, other than humans, who suffer from Alzheimer's disease and related dementias. It certainly is not Barr's burden during claim construction to disprove the patent specification. Rather, it is Barr's duty to construe the terms in accordance with the patent specification, which is why Barr has construed the term "patient" to mean "mammals, including humans."

Furthermore, Plaintiffs point to no authority to support their assertion that Barr has an obligation to put forth expert evidence on the meaning of "patient" in order for the term to be "at issue" for claim construction. This is no doubt due to the fact that it is established law that, in many instances, the resort to extrinsic evidence at all, including expert testimony and opinion, is unnecessary for purposes of claim construction. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581 (Fed. Cir. 1996). Indeed, it is a "rare circumstance" where the court is unable to

determine the meaning of a disputed claim term after assessing the intrinsic evidence alone. *Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268-69 (Fed. Cir. 2001). The term "patient" is at issue because it is part of claim 1 and Plaintiffs have asserted claim 1 against Barr.

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For all these reasons, Barr's construction of "patient" should be adopted.

C. "Method of Treating"

Contrary to Plaintiffs' assertion, Defendants do not agree that the term "method of treating" is a limitation of claim 1 of the '318 patent. (Plaintiffs' Br. at 11). As Defendants have stated in their opening brief, "*[t]o the extent the term is a limitation at all*, the term should be given its plain and ordinary meaning to a person of ordinary skill in the art." (Defendants' Br. at 10). It is Defendants' position that the term "treating" is not a claim limitation because it is in preamble and the term does not add meaning to the rest of the claim. *See Eaton Corp. v. Rockwell Int'l. Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (noting that in situations where the body of the claim sets out the complete invention, then the language of the preamble is often superfluous.).

Even if the term is a limitation, Plaintiffs do not appear to dispute Defendants' construction that "method of treating" in the context of the '318 patent means administration of galanthamine to improve the cognitive function or functional status of a patient with Alzheimer's

disease or related dementias. The disagreement arises in Plaintiffs' attempts to import limitations into the term that do not exist in the claims or the specification, *i.e.*, "alleviating the symptoms or deferring the decline" and "in a manner that is safe, tolerable, and produces clinically meaningful results." (Plaintiffs' Br. at 11).

Regarding their vague term "alleviating the symptoms," Plaintiffs look to the following quote from the summary of the invention: "A method of treating Alzheimer's disease and related dementias which comprises administering to mammals, including humans, an effective Alzheimer's disease cognitively-enhancing amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof." (Plaintiffs' Br. at 12 (quoting from the '318 patent, 1:45-50)). Plaintiffs then make the bold assertion that the "specification thus makes clear that the claimed treatment of Alzheimer's disease *includes alleviation of the patient's cognitive decline* in a therapeutic way." (Plaintiffs' Br. at 12 (emphasis added)). As can be seen easily by looking at the quoted part of the patent, that is not what it says. Moreover, Plaintiffs offer no other support for this proclamation. Thus, Plaintiffs are still hopelessly vague as to what they mean by "alleviating the symptoms" and certainly have not provided any legitimate intrinsic or extrinsic evidence as support.

Regarding the term "deferring the decline associated with Alzheimer's disease," Plaintiffs have offered no explanation of this term in their brief, and certainly point to no intrinsic or extrinsic evidence as support. Indeed, Plaintiffs do not discuss this term at all in their brief. That is not surprising, given the fact that nowhere in the patent or the prosecution history is there any indication that the inventor intended the word "treating" to mean deferring the progression of the disease state. Indeed, if the Court were to construe "treating" as including

"deferring the decline associated with Alzheimer's disease," that would give Dr. Davis credit for an invention she did not possess when she filed her patent application.

Plaintiffs have attempted to import further limitations into the term "method of treating" to include "in a manner beneficial to the patient – that is in a manner that is safe, tolerable, and produces clinically meaningful results." Again, Plaintiffs are importing limitations into the word "treating" that are not supported by either the intrinsic or extrinsic evidence.

Significantly, Plaintiffs do not provide any guidance as to what they mean by "clinically meaningful." Plaintiffs have failed to provide specificity as to the meaning of this term no doubt because the term "clinically meaningful" does not appear anywhere in the claims, specification, or prosecution history of the '318 patent. Plaintiffs' proposed inclusion as a limitation on the term "method of treating" is completely unwarranted. The prosecution history makes clear that the utility of the invention disclosed in the '318 patent rested on the expectation "that treatment with galanthamine [would] result in an improvement in the condition of those suffering from Alzheimer's disease." (Amendment Responsive to Office Action of April 10, 1986, attached to the Farnan Declaration as Exhibit 5). The condition that was the subject of the invention was cognition or functional status. There is *nothing* in the patent to suggest that such an improvement must further be "clinically meaningful" nor is there any suggestion as to what a "clinically meaningful improvement" would encompass. Construing the term "method of treating" to include some "clinically meaningful" aspect unnecessarily limits the scope of the claimed invention.

As for Plaintiffs' attempt to import safety and tolerability requirements to the word "treating," Plaintiffs miss the mark. Lacking any intrinsic evidence to support their proposed construction of "treating," Plaintiffs resort to arguing that "safety and tolerability is inherent in

the concept of treatment and implied, as well, by the restriction in the claim to 'pharmaceutically acceptable' salts of galantamine." (Plaintiffs' Br. At 12). Plaintiffs do not offer any record cites for this statement nor do they cite to any expert reports or testimony in support of this statement. Plaintiffs have not done so because the statement is not true. "Treatment" does not inherently imply that the treatment is safe and tolerable. The treatment of cancer is a perfect example. The drugs used to treat cancer are highly toxic and produce devastating and debilitating side-effects. The drugs, nonetheless, are a treatment for cancer because they attack the underlying condition.

In this case, there is nothing in the '318 patent that mentions or refers to any studies involving the safety or tolerability of galanthamine in Alzheimer's disease patients. Rather, the sole focus of the limited written description of the invention is that galantamine will improve the cognitive function/functional status of a patient with Alzheimer's disease and related dementias. The patent is silent on safety and tolerability.

Although they do not say so expressly, it appears that what Plaintiffs are attempting to do with their safety and tolerability requirement is to incorporate Food and Drug Administration ("FDA") requirements into the claim limitations of the '318 patent, presumably because they believe it will help them avoid a wealth of invalidating prior art. It will not. Moreover, there is no indication in the intrinsic evidence that the invention disclosed in the '318 patent has to meet the FDA's standards for safety and tolerability.

That Plaintiffs' proposed construction of "treating" is wrong is evidenced further by the remaining claims in the '318 patent. If one were to read the preamble language "method of treating" of claim 1 of the '318 patent to include safety and tolerability, the other claims of the '318 patent would be invalid.[4] For instance, dependent claim 5 states:

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[4] It is perfectly appropriate to look at claims other than those being asserted in the litigation at issue. "Other claims of the patent in question, *both asserted and unasserted*, can also be valuable sources of enlightenment as to

> "A method of according to claim **4**, wherein said dosage rate of 100-600 mg per day."

Dependent claim 4 states:

> "A method according to claim **1**, wherein said administration is oral and is in the range of 10-2000 mg per day."

It is well settled that "[a] claim in dependent form shall be construed to incorporate by reference *all limitations* of the claim to which it refers." 35 U.S.C. § 112 (emphasis added). Furthermore, a dependent claim cannot be broader than the independent claim on which it depends. *Trinity Indus., Inc. v. Road Sys. Inc.*, 121 F. Supp. 2d 1028, 1048 (E.D. Tex. 2000). As a dependent claim, Claim 5 incorporates *all of the limitations* of Claim 1. Therefore, the invention claimed in Claim 5 is "a method of treating Alzheimer's disease and related dementias," by administering "a therapeutically effective amount" of galanthamine.

With this in mind, the errors in Plaintiffs' construction of the term "method of treating" become readily apparent. In order to incorporate all of the limitations of claim 1 (as proposed by Plaintiffs), at a minimum, the administration of 100 mg/day of galanthamine must be "safe, tolerable, and produce clinically meaningful results." This, however, is not the case. Plaintiffs and their experts do not and cannot contend that it is.

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the meaning of a claim term." *Phillips v. AWH Corp.*, 415 F 3d 1303, 1314 (Fed. Cir. 2005) (emphasis added). The Federal Circuit has used unasserted, dependent claims to "aid in interpreting the scope of claims from which they depend." *Laitram Corp. v. NEC Corp.*, 62 F.3d 1388, 1392 (Fed. Cir. 1995) (noting that "[a]lthough each claim is an independent invention, dependent claims can aid in interpreting the scope of claims from which they depend.").

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Plaintiffs contend that dose titration inherently discloses a safety and tolerability requirement in the '318 patent. (Plaintiffs Br. at 12). However, this is merely a subjective attempt to import a novel meaning into a claim term without expressly doing so. The Federal Circuit has made it clear that "[w]hat a patentee subjectively intended his claims to mean is largely irrelevant to the claim's objective meaning and scope." *Akamai Techs., Inc.*, 344 F. 3d at

1194. The reference to dose titration would not have caused one of ordinary skill in the art to view safety or tolerability as part and parcel of a method of treating.[5]

In essence, Plaintiffs' definition of the term "method of treating" is a transparent effort to avoid a wealth of invalidating prior art by importing a novel meaning. If Dr. Davis intended to impart a novel meaning to the term "method of treating," there should be evidence supporting this novel construction of the term at issue. *Akamai Techs., Inc. v. Cable & Wireless Internet Svs., Inc.*, 344 F.3d 1186, 1194 (Fed. Cir. 2003) (Absent evidence that a patentee unequivocally imparted a novel meaning to [the] term or express relinquished claim scope during prosecution," the Federal Circuit gives "the limitation its full ordinary and customary meaning."). However, Plaintiffs have presented no evidence to support the idea that a "method of treating" includes safety or tolerability. Consequently, the Court should reject Plaintiffs' proposed construction and should construe the term "method of treating" as meaning "administration of a drug product (*i.e.* galanthamine) to improve the cognitive function or functional status of a patient with Alzheimer's disease or related dementias."

D. Therapeutically Effective Amount

Construction of the term "therapeutically effective amount" is closely tied to construction of the term "method of treating" discussed above. This is why Defendants proposed that the term be construed as follows: an amount sufficient to produce the desired therapeutic change or effect – *i.e.*, improve cognitive function/functional status – in a patient with Alzheimer's disease and related dementias. Nothing in Plaintiffs' Opening Claim Construction Brief refutes that this construction is the proper one for the Court to adopt. That is because Defendants' construction is based on the '318 patent specification. While describing her invention, Dr. Davis stated that,

[5] Claim 5 further undermines Plaintiffs' titration argument as the low end of the dose range of claim 5 is 100 mgs. daily, which would be neither safe, tolerable or effective, as set forth above.

"[i]t is an object of the present invention to improve the cognitive function of patients with Alzheimer's disease." (Ex. 1 at 1:41-42). She also stated that, prior to her invention, "there is no effective means of improving the functional status of persons with the disease." (Ex. 1 at 1:38-40). Therefore, the desired therapeutic change or effect is an improvement in cognitive function/functional status.

Plaintiffs, on the other hand, do not appear to base their unhelpful construction of "therapeutically effective amount" on much: "an amount sufficient to cause a therapeutically beneficial effect on symptoms of Alzheimer's disease and related dementias." Plaintiffs have failed to explain to what "beneficial effect" means. In their brief, Plaintiffs appear to believe that the "beneficial effect" is only improving the cognitive function of patients. (Plaintiffs' Br. at 10). Plaintiffs, however, ignore the inventor's statement regarding the desire of improving functional status. (Ex. 1 at 1:38-40).[6] Therefore, Plaintiffs' construction is incomplete and, thus, the Court should adopt Defendants' proposed construction of "therapeutically effective amount."

III. CONCLUSION

For the foregoing reasons, Barr respectfully requests that this Court adopt all of Barr's proposed claim constructions and reject Plaintiffs' proposed claim constructions.

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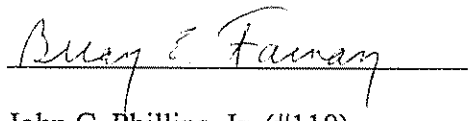
[6] **REDACTED**

Dated: December 27, 2006

Respectfully submitted,



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